REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claim 42 was previously cancelled. Claim 43 has been amended to delete the quotation marks. Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1-7, 9-14, 17-22 and 28-47 will be under examination, with claims 8, 15, 16, 23-27 and 48-108 withdrawn from consideration.

II. Rejection of Claim under 35 U.S.C. §112, second paragraph

The rejection of claim 43 under 35 U.S.C. §112, second paragraph, is maintained for the recitation of the "undefined" term "bioequivalency". Applicants respectfully traverse the rejection.

Bioequivalence is clearly defined in 21 C.F.R. § 320.1(e), as evidenced by an excerpt of §320.1 (submitted herewith as Exhibit A). For better clarification, claim 43 has been amended to delete the quotation marks. Because the meaning of the term "bioequivalency" is well known to one skilled in the art, Applicants respectfully request withdrawal of the rejection.

III. Rejection of Claims under 35 U.S.C. §102(b)

The rejection of claims 1-5, 7, and 9-13 over Krause *et al.*, *Int. J. Pharmaceutics* 27: 145-155, 1985 ("Krause"), under 35 U.S.C. §102(b) is maintained. Applicants respectfully traverse the rejection.

The Examiner acknowledges that Krause "does not explicitly state the size of the triamcinolone particles," but contends that "it is ***inherently*** interpreted that given the triamcinolone drug are [*sic*] encapsulated inside the PLA" (Office Action, page 3, lines 2-4). Applicants respectfully disagree.

According to the requirements set forth in the MPEP, the Examiner must provide a rationale or evidence to show inherency. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "***To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.***' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)" (MPEP 2112, emphasis added).

In the present case, the Examiner's allegation of the prior-art teaching of the particle size is based on the interpretation of triamcinolone encapsulated inside the PLA, which entails only one possibility of the relationship between the tramcinolone and the PLA particles. In fact, the Examiner's own statement bridging pages 5 and 6 of the Office Action is a salient admission that the prior-art teaching reflects "probabilities and possibilities": "[i]t is also interpreted that

loading of triamcinalone acetonide entails both encapsulation and adsorption of PLA unto triamcinolone acetonide." Therefore, the particle size of triamcinolone cannot be an "inherent" feature of Krause's composition.

To further support the possibilities of the composition in Krause, Krause describes that "...on [the] one hand drug was released from the interior of the particles during washing. On the [other] hand, due to the very minute diameter of the [PLA] particles they have ***a large surface on which the greatest amount of drug was located***" (page 152, lines 2-5, emphasis added). Accordingly, one skilled in the art would be left to interpret the possibilities of the configuration of the composition and thus could not have made clear that the missing descriptive matter (i.e., the claimed particle size) is necessarily present in the subject matter described (the composition of Krause). Therefore, Krause sets forth no limitation on the drug particle size to anticipate (expressly or **inherently**) the claimed invention, since triamcinolone particles of different sizes might be loaded differently, either inside or on the surface of the PLA particles.

Moreover, the Examiner's contention that triamcinolone is ***encapsulated*** inside the PLA fails to meet the claim limitation that at least one surface stabilizer is ***adsorbed on the surface*** of the triamcinolone particles.

Because the rejection is based on a faulty rationale, and because the cited reference does not teach or suggest the claimed invention, Applicants respectfully request withdrawal of the rejection.

V. Rejection of Claims under 35 U.S.C. §103(a)

A. Krause and Radhakrishnan

Claims 1-5, 7, 9-14, 18-21, 28-41, and 43-47 are rejected under 35 U.S.C. §103(a) over Krause in view of U.S. Patent No. 5,049,389 to Radhakrishnan ("Radhakrishnan"). Applicants respectfully traverse the rejection.

Krause is discussed *supra*. Radhakrishnan is cited for the alleged teaching of a combination of other anti-inflammatory drugs. Because Radhakrishnan does not cure the deficiency of Krause noted above, the combined teaching of the cited references does not render the claimed invention obvious. Withdrawal of this ground for rejection is respectfully requested.

B. Krause, Radhakrishnan and Unger

Claims 6, 17 and 22 are rejected under 35 U.S.C. §103(a) over Krause in view of Radhakrishnan and U.S. Patent No. 5,542,935 to Unger *et al.* ("Unger"). Applicants respectfully traverse the rejection.

Krause and Radhakrishnan are discussed *supra*. Unger is cited for the alleged teachings of topical administration, specific anti-inflammatory agents and surface stabilizers. However, this reference fails to remedy the deficiencies of Krause and Radhakrishnan. Therefore, the claimed invention is non-obvious over the cited art.

In view of the foregoing, Applicants respectfully request the rejections under 35 U.S.C. §103(a) be withdrawn.

V. Provisional Non-Statutory Double Patenting Rejection

Claims 1, 4-7, 9-12, 14, 18-21, and 28-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-15, 17-20 and 22-41 of copending Application No. 10/683,154. Applicants respectfully traverse the rejection.

Because this rejection is provisional, Applicants choose to defer any action until the Examiner indicates that the present application is otherwise allowable.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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